EYE DROPS ADVANCED RELIEF- tetrahydrozoline hydrochloride, polyethylene glycol 400, dextran 70, povidone solution/ drops KC Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredients

Dextran 70 0.1%

Polyethylene glycol 400 1%

Povidone 1%

Tetrahydrozoline HCl 0.05%

Purposes

Dextran 70.....Lubricant

Polyethylene glycol 400....Lubricant

Povidone.....Lubricant

Tetrahydrozoline HCl......Redness reliever

Uses

- relieves redness of the eye due to minor eye irritations
- as a lubricant to prevent further irritation or to relieve dryness of the eye

Warnings

For external use only

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- to avoid contamination, do not touch tip of container to any surface.

Replace cap after using.

- if solution changes color or becomes cloudy, do not use
- overuse may produce increased redness of the eye
- remove contact lens before using

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for

more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

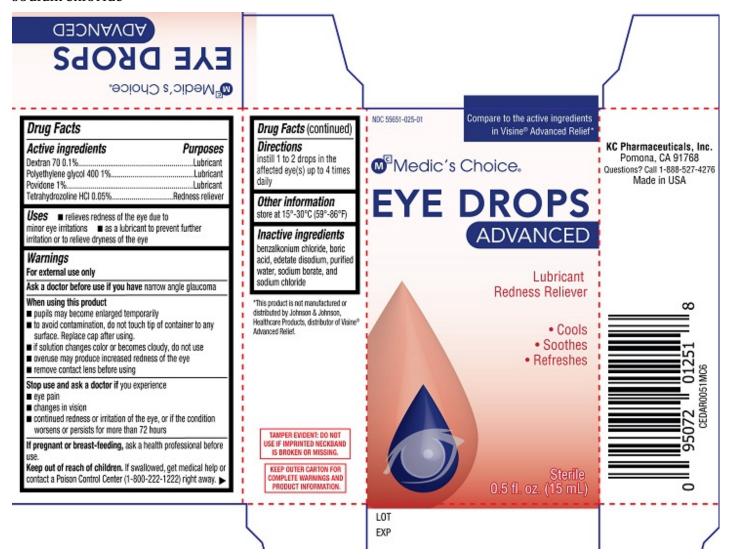
instill 1 to 2 drops in the affected eye(s) up to 4 times daily

Other information

store at 15°-30°C (59°-86°F)

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, and sodium chloride



EYE DROPS ADVANCED RELIEF

400 - UNII:B697894SGQ)

tetrahydrozoline hydrochloride, polyethylene glycol 400, dextran 70, povidone solution/ drops

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (S	ource)	NDC:55651-	025
Route of Administration	OPHTHALMIC				
Active Ingredient/Active Mo	ietv				
					Strength
ū .			Dasis 01 Sti	engtn	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL			DOI VETUVI ENE C	LVCOL 400	10 mg

POLYETHYLENE GLYCOL 400

in 1 mL

TETRAHYDRO ZO LINE HYDRO CHLO RIDE (UNII: 0 YZT43HS7D) (TETRAHYDRO ZO LINE - UNII:S 9 U0 25 Y0 77)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL
DEXTRAN 70 (UNII: 7SA290 YK68) (DEXTRAN 70 - UNII:7SA290 YK68)	DEXTRAN 70	1 mg in 1 mL
PO VIDO NE (UNII: FZ989GH94E) (PO VIDO NE - UNII: FZ989GH94E)	POVIDONE	10 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
BORIC ACID (UNII: R57ZHV85D4)				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)				
WATER (UNII: 059QF0KO0R)				
SODIUM BORATE (UNII: 91MBZ8H3QO)				
SO DIUM CHLO RIDE (UNII: 451W47IQ8 X)				

Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:55651-025- 01	1 in 1 CARTON	12/09/2003		
	L	15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part349	12/09/2003		

Labeler - KC Pharmaceuticals, Inc. (174450460)

Establishment				
Name	Address	ID/FEI	Business Operations	
KC Pharmaceuticals, Inc.		174450460	manufacture(55651-025), pack(55651-025), label(55651-025)	

Revised: 10/2019 KC Pharmaceuticals, Inc.